REMARKS

In the Office Action, Claims 1, 10 and 16 are objected; Claims 5-22 are provisionally rejected under 35 U.S.C. §101; Claims 2-4 are rejected under 35 U.S.C. §112; and Claims 1-22 are rejected under 35 U.S.C. §103. Claims 1, 4, 10 and 16 have been amended. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made**." Applicants believe the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, Claims 1, 10 and 16 are objected for alleged informalities. As previously discussed, Claims 1, 10 and 16 have been amended. In view of same, Applicants believe that the alleged informalities have been addressed. Applicants note that the changes made to Claims 1, 10 and 16 are for clarification purposes and thus do not have a narrowing effect on the scope of the claimed subject matter. Further, Applicants do not intend to disclaim any subject matter via the amendment. Therefore, Applicants believe that the objection should be withdrawn.

In the Office Action, Claims 5-22 have been provisionally rejected under 35 U.S.C. §101. The Patent Office alleges that Claims 5-22 of the present application claim the same invention as that of Claims 5-22 of co-pending Application No. 09/206,063.

Applicants believe that the provisional rejection of Claims 5-22 under 35 U.S.C. § 101 is improper. Of the pending claims at issue, Claims 5, 11 and 17 are the sole independent claims. Claim 5 relates to a method of administering an autoclavable osmotic agent to a subject in need thereof; and Claims 11 and 17 relate to a method of administering a sterilizable osmotic agent to a subject in need thereof. In comparison, Claims 5-22 of U.S. Patent Application No. 09/206,063 relate to methods of preparing a stabilized osmotic agent. In view of same, Applicants do not believe that Claims 5-22 of the present application and Claims 5-22 of U.S. Patent Application No. 09/206,063 should be considered the same invention pursuant to 35 U.S.C. § 101.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 2-4 are rejected under 35 U.S.C. §112, second paragraph. The Patent Office alleges that the claim term "substantially" renders Claims 2-4 indefinite in meaning.

Applicants believe that this rejection is improper. Clearly, one skilled in the art would consider the term "substantially free" to mean any negligible amount of formaldehyde (Claim 2), furfurals (Claim 3) or terminal aldehyde groups (Claim 4) that may remain in the peritoneal dialysis solutions of the claimed invention. Further, Applicants note that Claim 4 has been amended to include the term "free" as fully supported in the specification. Applicants believe that this amendment is for clarification purposes and thus does not have a narrowing effect on the scope of the claimed subject matter. Applicants do not intend to disclaim any subject matter via the amendment. Therefore, Applicants believe that the claimed invention as defined in Claims 2-4 is definite in meaning and scope.

Accordingly, Applicants respectfully request that the rejection of Claims 2-4 under 35 U.S.C. §112, second paragraph be withdrawn.

In the Office Action, Claims 1-4 are rejected under 35 U.S.C. §103 as being allegedly unpatentable over U.S. Patent No. 4,886,789 ("*Milner*") and European Patent Document No. 0 612 528 ("*Bellini*"). The Patent Office primarily relies on *Milner* and thus relies on *Bellini* to remedy the deficiencies of *Milner*.

Applicants believe that this rejection is improper. Of the pending claims at issue, Claim 1 is the sole independent claim. Claim 1 relates to a sterilized peritoneal dialysis solution. The solution includes a starch that comprises a glucose polymer, such as D-glucitol, gluconic acid or alkylglycoside each having a formula as defined in Claim 1. The glucose polymer is linked by α-1,4 bonds that include at least 85%, by number, of the linkages. The peritoneal dialysis solutions of the present invention are stable under autoclaving and sterilization conditions, such as steam sterilization conditions. See, Specification, page 7, lines 8-14.

In contrast, Applicants believe that the cited art is clearly deficient with respect to a number of features of the claimed invention. At the outset, *Milner* merely discloses the use of glucose polymers as a substitution for dextrose. *Milner* does not address the problem of the decomposition of glucose or glucose polymers during sterilization or autoclaving procedures. While *Milner* may suggest the use of glucose polymers, nowhere does *Milner* disclose or suggest the use of glucose polymers that are linked by bonds that include at least 85%, by number, α –1, 4 bonds as required by the claimed invention.

Indeed, *Milner* merely refers to α –1, 6 bonds. See, *Milner*, for example, column 3, line 9. Moreover, *Milner* fails to disclose the specific type of glucose polymer, namely, D-glucitol,

gluconic acid or alkylglycoside, as required by the claimed invention. Therefore, for at least these reasons, *Milner* is clearly deficient with respect to the claimed invention.

Further, *Bellini* is merely recited for the proposition that it teaches the use of gluconic acid in a peritoneal dialysis solution. However, Applicants believe that *Bellini* fails to disclose or suggest a glucose polymer linked by at least 85%, by number, α –1, 4 bonds as required by the claimed invention. Thus, *Bellini* cannot be relied on to remedy the deficiencies of *Milner*. Based on at least these noted differences between the cited art and the claimed invention, Applicants believe that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 5-22 are rejected under 35 U.S.C. 103 as being unpatentable over SOLOMONS, Organic Chemistry, 2nd edition, 1976, p. 890 ("*SOLOMONS*") in combination with AMAN et al., Carbohydrates in Food, p. 195, 1996 ("*AMAN*") and U.S. Patent No. 3,974,034 ("*HORN*"). The Patent Office primarily relies on *SOLOMONS* and thus relies on the other cited art to remedy the deficiencies of *SOLOMONS*.

Applicants believe that this rejection is improper. Of the pending claims at issue, Claims 5, 11 and 17 are the sole independent claims. As previously discussed, Claim 5 relates to a method of administering an autoclavable osmotic agent to a subject in need thereof; and Claims 11 and 17 relate to a method of administering a sterilizable osmotic agent to a subject in need thereof. Claim 5 further recites that the osmotic agent is prepared by providing a solution of starch dissolved in water; and adding $NaBH_4$ to the starch solution to reduce the starch.

Claim 11 further recites that the osmotic agent is prepared by providing a solution of starch dissolved in water; providing a solution of NaOCl; and adding the NaOCl solution the starch solution to oxide the starch. Claim 17 recites that the osmotic agent is prepared by dissolving starch in an acid and an alcohol selected from the group consisting of methanol, butanol, and glycerol.

As noted in the Applicants' patent application, it is known to use dialysis solutions including glucose as an osmotic agent. However, there are certain disadvantages to using glucose as an osmotic agent. In this regard, glucose decomposes in an aqueous solution during autoclaving or steam sterilization.

Thus, substitutes for glucose as an osmotic agent have been sought and proposed. One substitute that has been suggested is icodextrins. However, while these compounds (icodextrins) are suitable for use as osmotic agents, there are issues associated with their use. For example, when heated icodextrins form aldonic acids and formaldehyde. The presence of formaldehyde in peritoneal dialysis solution is inappropriate due to its poor biocompatibility. Thus, the use of icodextrins, including maltodextrins, as a substitute for glucose as an osmotic agent has been unsatisfactory.

Applicants' respectfully submit that the present invention deals with this issue by providing methods for administering a stabilized osmotic agent composed of icodextrins. The stabilized nature of the osmotic agent of the present invention allows the osmotic agent to be autoclavable and sterilizable. In this regard, the icodextrins prepared by the methods of the claimed invention can be effectively used as osmotic agents and administered to subjects in need thereof.

Applicants respectfully submit that the cited references, even if combinable, fail to disclose a number of features of the claimed invention. As the Patent Office admits, the cited references merely disclose: the use of sodium borohydride to reduce saccharides (See, *Solomon*); the extraction of non-cellulosic polysaccharides using alkali solutions (See, *Aman*); and that oxidation of starch leads to a product that is more easily solubilized and has a lower viscosity (See, *Horn*).

Based on same, Applicants question how the Patent Office can even consider that the references, alone or combined, disclose or suggest each and every feature of the claimed invention. In this regard, Applicants respectfully submit that the Patent Office has improperly failed to give patentable weight to the administration of an autoclavable or sterilizable osmotic agent as recited in the preamble of Claims 5-22.

As such, the prior art must suggest a method of administering an autoclavable or sterilizable osmotic agent. Indeed, Applicants do not believe that any one of the references at the cited portions even uses the words "osmotic agent" let alone the administration thereof to a subject in need. How can the references thereby suggest the claimed invention?

Moreover, Applicants respectfully submit that the present invention deals with a recognized problem in the art by providing methods for administering stabilized osmotic agents composed of icodextrins. If stabilized, the osmotic agent is autoclavable and thus sterilizable. In

this regard, Applicants have uniquely discovered that autoclavable or sterilizable osmotic agents composed of icodextrins can be prepared such that they can be effectively administered to a subject in need.

Contrary to the Patent Office's position, Applicants respectfully question how the differences between the cited references and the claimed invention would otherwise be obvious when, for example, not one of the references deals with the issues involved with an osmotic agent, let alone the administration thereof; not one of the references deals with stabilizing an osmotic agent, let alone the administration thereof; not one of the references deals with the problems of a non-sterilizable osmotic agent that is heated; and not one of the references relates to a stabilized icodextrin that is autoclavable and thus sterilizable, let alone the administration thereof. Applicants respectfully question why would the art therefore suggest to anyone, let alone one skilled in the art, at the time of the claimed invention, to modify the references to provide a method of administering an autoclavable or sterilizable osmotic agent to a subject in need thereof. Therefore, Applicants believe that the cited art is clearly deficient with respect to the claimed invention.

Based on at least these noted differences between the cited art and the claimed invention, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the rejection should be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30, 142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

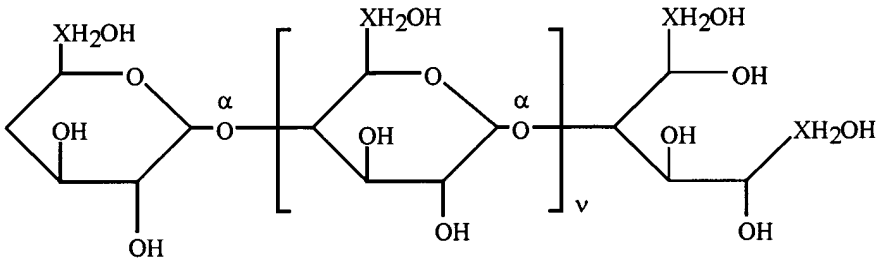
VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

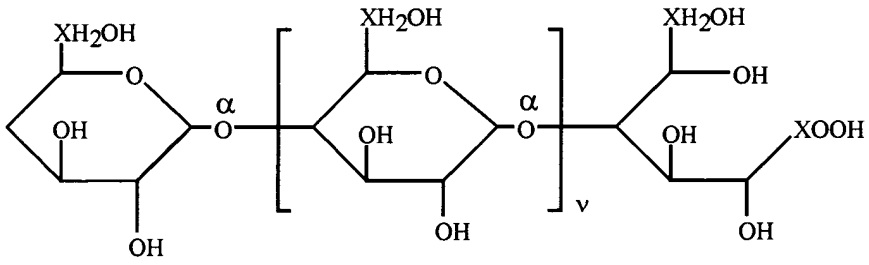
Claims 1, 4, 10 and 16 have been amended as follows:

1. (Amended) A sterilized peritoneal dialysis solution comprising:

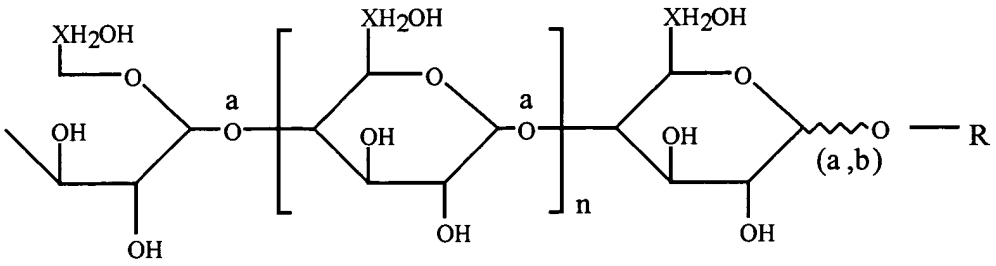
a starch comprising a glucose polymer selected from the group consisting of D-glucitol having the formula~~:~~



and gluconic acid having the formula



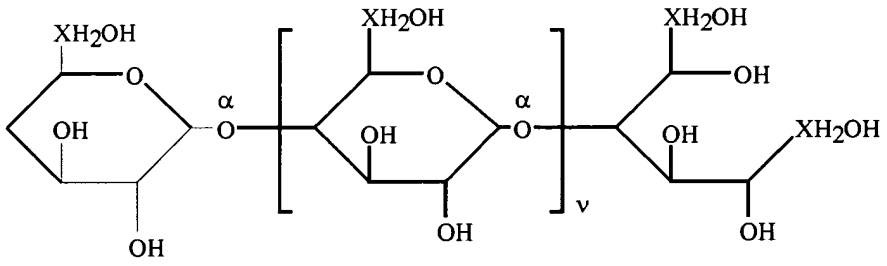
and alkylglycoside having the formula



wherein R is selected from the group consisting of CH_3, CH_3CH_2, $(CH_2OH)_2CH$, $CH_2(OH)CH(OH)CH_2$, and $[CH_2(OH)CH(OH)CH_2(OH)]CH$, and wherein the polymer is linked by α-1,4 bonds, that comprise at least 85%, by number, of the linkages.

4. (Amended) The peritoneal dialysis solution of claim 1 wherein the partially hydrolyzed starch is substantially free of terminal aldehyde groups.

10. (Amended) The method of claim 5 wherein the starch is reduced to an icodextrin linked predominately by α-1,4 bonds and having the formula:



16. (Amended) The method of claim 11 wherein the starch is oxidized to an icodextrin linked predominately by α-1,4 bonds and having the formula: